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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,449	03/28/2000	KATSUMI AOYAGI	594.352USWO	8016

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/509,449

Applicant(s)

AOYAGI ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20, 21, 23 is/are rejected.
- 7) ☒ Claim(s) 22 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Currently, claims 18 and 20-24 are pending and under consideration.
2. Claims 18-22 were pending and rejected in the prior action, the Final Action mailed on February 23, 2005.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2005 has been entered. In this submission, the Applicant amended claim 18, cancelled claim 19, and added new claims 23 and 24.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **(Prior Rejection- Withdrawn)** Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Masalova et al., J Med Virol (of record in the action mailed

Art Unit: 1648

on September 27, 2001) in view of Papatheodoridis et al. (J Hepatol 24: 36-41), and further in view of the teachings of Ling et al. (GB 2 051 357), and of Schönbrunner (GB 2 313 666). In view of the limitation of the claim to the use of antibodies targeting specific peptide sequences, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claim 18 was rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al. (WO 93/10239) in view of Ling and Schönbrunner. In view of the limitation of the claim to the use of antibodies targeting specific peptide sequences, the rejection is withdrawn.

7. **(Prior Rejection- Maintained)** Claims 19 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner, and further in view of either Lacroix (EP 0 507 615) or Seidel et al. (U.S. Patent 6,183,949). In the Response, the Applicant has cancelled claim 19, and incorporated the limitations of this claim into claim 18, and has provided two arguments in traversal of the rejection. The rejection is therefore restated as a rejection of claims 18 and 20 over the teachings of either of (1) Masalova and Papatheodoridis, or (2) of Simmonds, in view of Ling and Schönbrunner, and further in view of either Lacroix (EP 0 507 615) or Seidel et al. (U.S. Patent 6,183,949).

First, the Applicant asserts that there is no motivation in the art for the use of antibodies of Lacroix or Seidel in the methods suggested by the other references. This argument is not found persuasive because the references do teach that antibodies directed to the disclosed peptides in these references may be used for the detection of HCV antigens. See, Lacroix, page 7

Art Unit: 1648

lines 41-53; and Seidel, column 6, lines 46-67. Further, as was described in the prior action (page 4) the teachings of Ling and Schönbrunner indicate that any marker of the target pathogen may be used in the simultaneous detection assays, so long as the detection antibodies and detection polypeptides are non-complementary. Thus, those in the art would have been motivated to use any known antibodies or peptides as markers useful for HCV detection in a combined antibody/antigen detection assay. Because Lacroix and Seidel identify their respective peptide sequences as targets for diagnostic antibodies, those of ordinary skill in the art would have recognized that the antibodies of these references would be useful in methods for the detection of HCV. Thus, the art provides adequate motivation for the use of such antibodies in methods for the detection of HCV as suggested by Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner. The Applicant's first argument in traversal is therefore not found persuasive.

The second argument in traversal appears to be an assertion that those of ordinary skill in the art would have had no reasonable expectation of success in the making or use of antibodies directed to the peptide antigens disclosed by Lacroix and Seidel. In particular, the Applicant asserts that these two references only teach that antibodies against these peptides may be produced, but do not actually do so. This argument is not found persuasive for two reasons. First, each of the references demonstrate that the peptide disclosed in the respective reference reacted with antibodies in serum samples. See e.g., Lacroix, pages 10-12; and Seidel, column 10 and Table II (columns 25 and 26). Because the peptides reacted with antibodies found in sera from immunized subjects, those of ordinary skill in the art would have had a reasonable expectation of success in the induction and isolation of such antibodies. Secondly, the application specifically

Art Unit: 1648

states that monoclonal antibodies directed to the disclosed antigenic peptides may be “easily prepared by those skilled in the art,” and that “[p]reparation of monoclonal antibodies from hybridomas is well known.” Page 9, lines 24-26. It is additionally noted that the means for producing antibodies disclosed in the present application (see e.g., page 8) are substantially the same as those described in the references. See e.g. Seidel, column 6 lines 46-60; and Lacroix, page 7 lines 41-53. In view of the above, and as the Applicant has provided no more than an unsupported assertion that those in the art would not have had a reasonable expectation of success in the making of the suggested antibodies, the Applicant’s traversal on this basis is also not found persuasive.

The rejection is therefore maintained for the reasons above, and for the reasons of record.

8. **(Prior Rejection- Maintained)** Claims 21 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either of Cheng et al. (U.S. 5,627,080). These claims have been amended as indicated with respect to claim 18 above. However, new claims 23 and 24 read on substantially the same subject matter as was previously encompassed by claims 21 and 22. The rejection is withdrawn from claim 22, maintained with respect to claim 21, and extended to new claim 23.

The Applicant traverses the rejection on the basis that the teachings of Cheng merely describe all kinds of detergents without directing those in the art to any specific detergent or detergents, particularly those in the claims, for use. This argument is found persuasive in part. With respect to the specific detergents identified in the present application (pages 23-27), it is

Art Unit: 1648

noted that the Applicant does appear to have demonstrated unexpected results when using non-ionic detergents with an HLB value of 12 to 14, and with detergents having alkyl chains of at least 10 carbon atoms and one or more secondary to quaternary amines. Because claim 22 is limited to detergents with the indicated alkyl chains and amines, the rejection is withdrawn from this claim.

However, these showings are not found persuasive with respect to claim 21. This is because the claim is drawn to the inclusion of any non-ionic detergent. The teachings of the Cheng references indicate that any of these detergents would be useful in an immunoassay. While the Cheng reference indicates that additional benefits may be seen with respect to certain types of assays, the teachings of the reference are not limited to those specific assay formats. In addition, the reference teaches that detergents of the types identified, and preferably non-ionic detergents, provide benefits to the sensitivity of immunoassays. Column 7 lines 27-36, and 52-53. Thus, as was indicated in the prior action, those of ordinary skill in the art would have been motivated and had a reasonable expectation of success in the inclusion of such detergents in an immunoassay.

It is noted that the Applicant asserts that the detergents used in the claimed methods are intended for a particular assay. However, as the teachings of Cheng are directed to immunoassays in general, this is insufficient to render the claims non-obvious. However, it is noted that the application demonstrates that certain non-ionic detergents are capable of the unexpected results as discussed in Tables 2 and 3, and on page 27. The application teachings that those non-ionic detergents with an HLB value of between 12 to 14, when included in .5 to 2% dilutions, improve the sensitivity of the assays to a greater degree than other surfactants. It is also

Art Unit: 1648

noted that, with respect to these detergents, those in the art already used them in immunoassays, albeit at a reduced concentration from the .5 to 2% shown in Table 2. See e.g., U.S. 5,811,525 columns 11 and 23 (teaching the use of either of the Triton® X-100 or Nonidet® P-40 detergents in a final concentration of below .5% in the immunoassay buffer). Nonetheless, the Applicant appears to have shown improved results for the particular class and solution dilutions identified on page 27 and in Table 2. Nonetheless, as the claims are not limited to this class or dilution of non-ionic surfactants, the rejection is maintained with respect to claim 21, and extended to claim 23.

Conclusion

9. No claims are allowed. Claims 22 and 24 are objected to as depending on rejected claims.
10. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

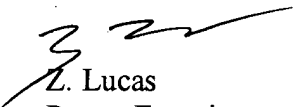
U.S. 4,639,425. This reference provides additional teaching relating to the use of detergents to improve immunoassays, and specifically teaches the use of Tween and Triton non-ionic detergents. Columns 1-2. However, it is noted that the reference also teaches the use of such detergents at lower concentrations than those indicated in Table 2 of the application.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

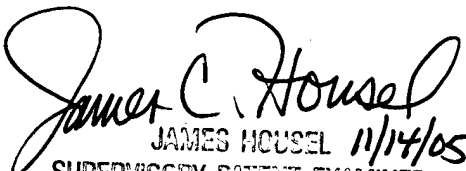
Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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SUPERVISORY PATENT EXAMINER
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